

REMARKS

Applicant thanks the examiner for carefully reviewing the application. Please reconsider this application in view of the following remarks.

Disposition of the Claims

Claims 1-9, 37-40, 43, 44, 49, and 50 are pending after the restriction requirement. Claims 1, 2, and 37 are independent. Claims 3-9, 38-40, 43, 44, 49, and 50 depend, directly or indirectly, from claim 1, 2, or 37.

Claim Rejections under 35 U.S.C. § 112

Claims 1-4, 6-9, and 49 are rejected under 35 U.S.C. § 112, ¶ 1, for failing to comply with the enablement requirement. This rejection is respectfully traversed.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). *See also*, M.P.E.P. § 2164.01.

The Examiner asserts that except for type II diabetes, the specification does not enabled the treatments for other disorders. The Examiner seems to hold that every disorder claimed needs to be described and enabled in the specification. However, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) (emphasis added). *See also*, M.P.E.P. § 2164.01.

Like type II diabetes, other disorders (e.g., obesity, dyslipidemia, metabolic syndrome and acne) also are linked to stearoyl-CoA desaturase (SCD) activity, and it has been shown that inhibition or knock out of SCD activity can reduce or alleviate these disorders. Since treating these SCD-associated disorders are well documented in the art, there is no need to repeat these facts in the specification.

For example, Park, E.I. *et al.*, *J. Nutr.* (1997), Vol. 127, pp. 566-573, demonstrated that mice provided with a diet that lowered the expression of stearoyl-CoA desaturase-1 had lower body weight and lower serum concentrations of total cholesterol, triglycerides, and HDL cholesterol. Furthermore, Ntambi *et al.*, *Proc. Natl. Acad. Sci.*, (August 20, 2002), Vol. 99, No. 17, pp. 11482-6, demonstrated that loss of stearoyl-CoA desaturase-1 function (activity) protected mice from gaining weight from a high-fat diet. Thus, one skilled in the art, having the disclosure of the present application and the IC₅₀ data, would not need undue experimentation to treat obesity (i.e., to lower body weights) or to lower serum cholesterol, triglycerids and HDL cholesterol.

Furthermore, WO 2001/062954 disclosed an animal model for testing SCD inhibitors in lowering triglyceride, LDL and VLDL serum levels (see Example 1) and demonstrated the correlation between SCD activity and levels of serum triglycerides in humans (see Example 2). Attie, A.D. *et al.*, *Journal of Lipid Research* (2002), Vol. 43, pp. 1899-1907 showed that SCD is the rate-limiting enzyme in triglyceride production. Similarly Miyazaki, M. *et al.*, *Journal of Lipid Research* (2001), Vol. 42, pp. 1018-1024, showed that triglyceride synthesis was dramatically reduced in the liver of SCD -/- mice fed a lipogenic diet compared to normal mice. Miyazaki, M. *et al.*, *J. Biol. Chem.* (2000), Vol. 275, No. 39, pp. 30132-30138, also showed similar results. These observations show that triglyceride synthesis is highly dependent upon the SCD activity and that inhibition of SCD activity can be used to lower triglyceride synthesis. Thus, one skilled in the art, having knowledge of the instant Specification and the IC₅₀ data of the claimed compounds, would not need undue experimentation to use the compounds of the invention to lower triglyceride, LDL, and VLDL in the serum to treat dyslipidemia.

Zheng *et al.*, *Nat. Genet.* (1999) 23:268-270, showed that rodents lacking a functional SCD1 gene had changes to the condition of their eyes, skin and coat, resulting in reduced sebum production. Excessive sebum production is a known cause of acne. As noted by Miyazaki *et al.*, *J. Nutr.* (2001), Vol. 131, pp 2260-68, SCD1-/- mice developed cutaneous abnormalities and atrophic sebaceous and meibomian glands, as compared to normal mice. These observations show that SCD activity is linked to sebum production and that inhibition of SCD activity can prevent excessive sebum production or acne. One skilled in the art, having read the disclosure of

the present invention, would not need undue experimentation to use compounds of the invention to treat acne.

From the above description, it is clear that the literature is replete with evidence of the links between SCD activity and various metabolic diseases that are associated with fatty acid metabolism. Because "*a patent need not teach, and preferably omits, what is well known in the art,*" Applicant believes it is unnecessary to describe these known facts in the specification.

As recognized by the Examiner, one skilled in the art is an MD's, Ph.D's, or one with advanced degrees and the requisite experience in treatment of disorders related to inhibition of human SCD. (Office Action, p. 3). Applicant respectfully submits that one skilled in the art, having the prior art knowledge and the disclosure of present invention, would not need undue experimentation to use compounds of the invention in treating SCD-mediated disorders. Accordingly, withdrawal of this rejection is respectfully requested.

Double Patenting

Claims 1-9, 37-40, 43-44, and 49-50 are provisionally rejected on the ground of obviousness type double patenting as being unpatentable over claims 1-9, 35-39, and 42-43 of co-pending application No. 10/566,857 (Pub No. 2006/0293308). Claims 1-9, 37-40, 43-44, and 49-50 are provisionally rejected on the ground of obviousness type double patenting as being unpatentable over claims 1-9, 38,40, 41, and 43-45 of co-pending application No. 10/567,009 (Pub No. 2006/0252767).

New terminal disclaimers are filed herewith. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591, Reference 17243/003001.

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Respectfully submitted,

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Attachments - 2 Terminal Disclaimers